

1/41

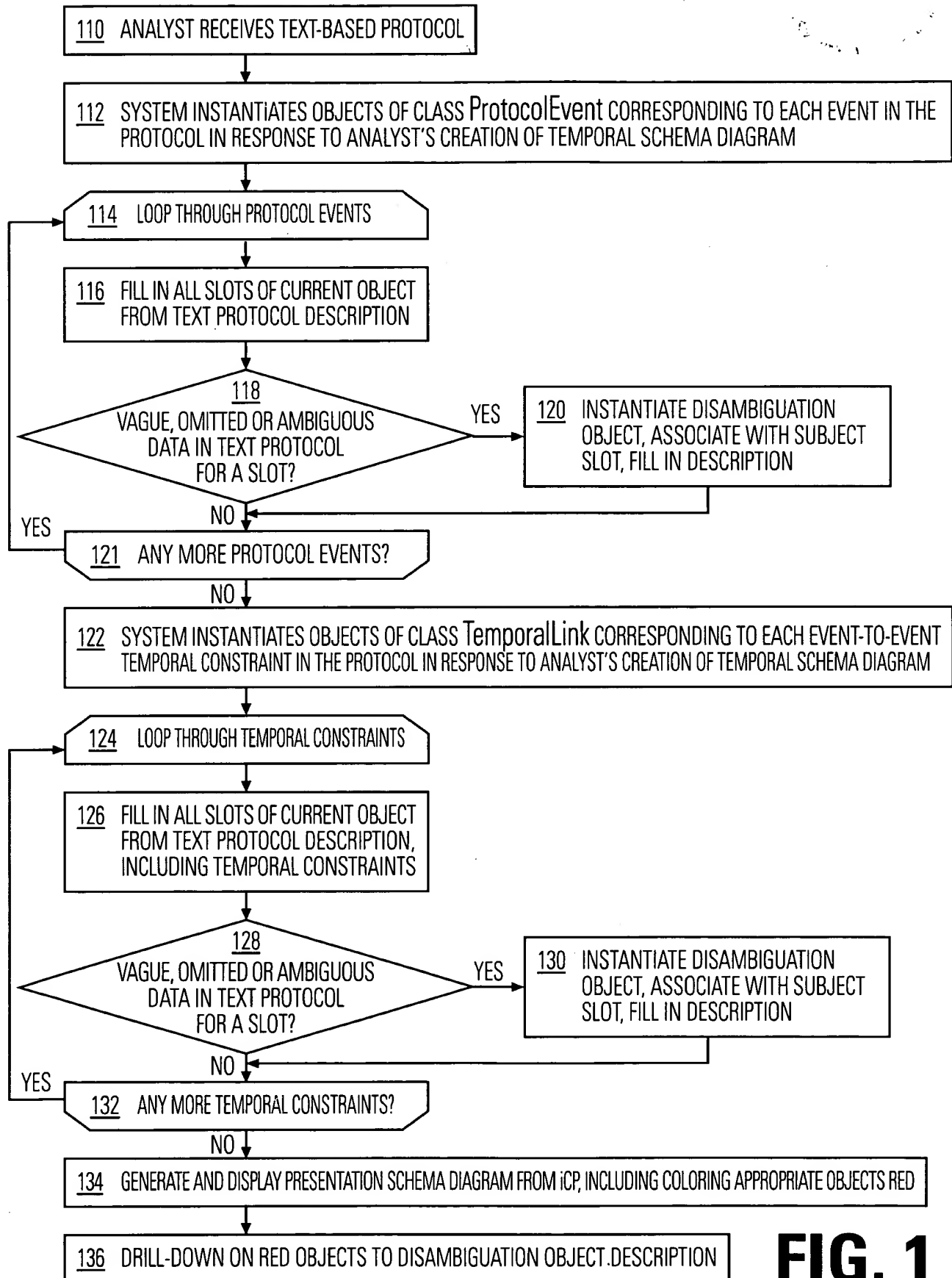


FIG. 1

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cancer_protocols_INSTANCE_00039 [instance of Cancer_Clinical_Protocol]	
Label	Version
CALGB 49802	mgk 25Jan00
Title	Authors
Phase III Study of Adriamycin/Taxotere vs Adriamycin/Cytosan for the Adjuvant treatment of Node Positive or High Risk Node Negative Breast Cancer	M.G. Public
Clinical Algorithm	Reference
CALGB 49802 Level 1	MUSC PRN web page
Context Reference	
Entry Criteria (1 values)	
Protocol Name	Inclusion List
CALGB 49802	<ul style="list-style-type: none">Histologically or cytologically confirmed invasive breast cancer1-3 histologically involved axillary lymph nodesNo evidence of metastatic disease (M0)Absolute neutrophil count of at least 1,500/mm³Platelet count of at least 100,000/mm³Left ventricular ejection fraction at rest at least 45% by MUGABilirubin no greater than 1.2 times upper limit of normal (ULN)Age 18-70Effective contraception required of fertile womenNo prior chemotherapyNo prior radiotherapyNo concurrent estrogen therapy
Clinical State Name	
Exclusion List	
<ul style="list-style-type: none">Tumor of any size with direct extension to chest wall or skin (T4)Patient is pregnant or nursing	

FIG. 2

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201120" FEB 2000

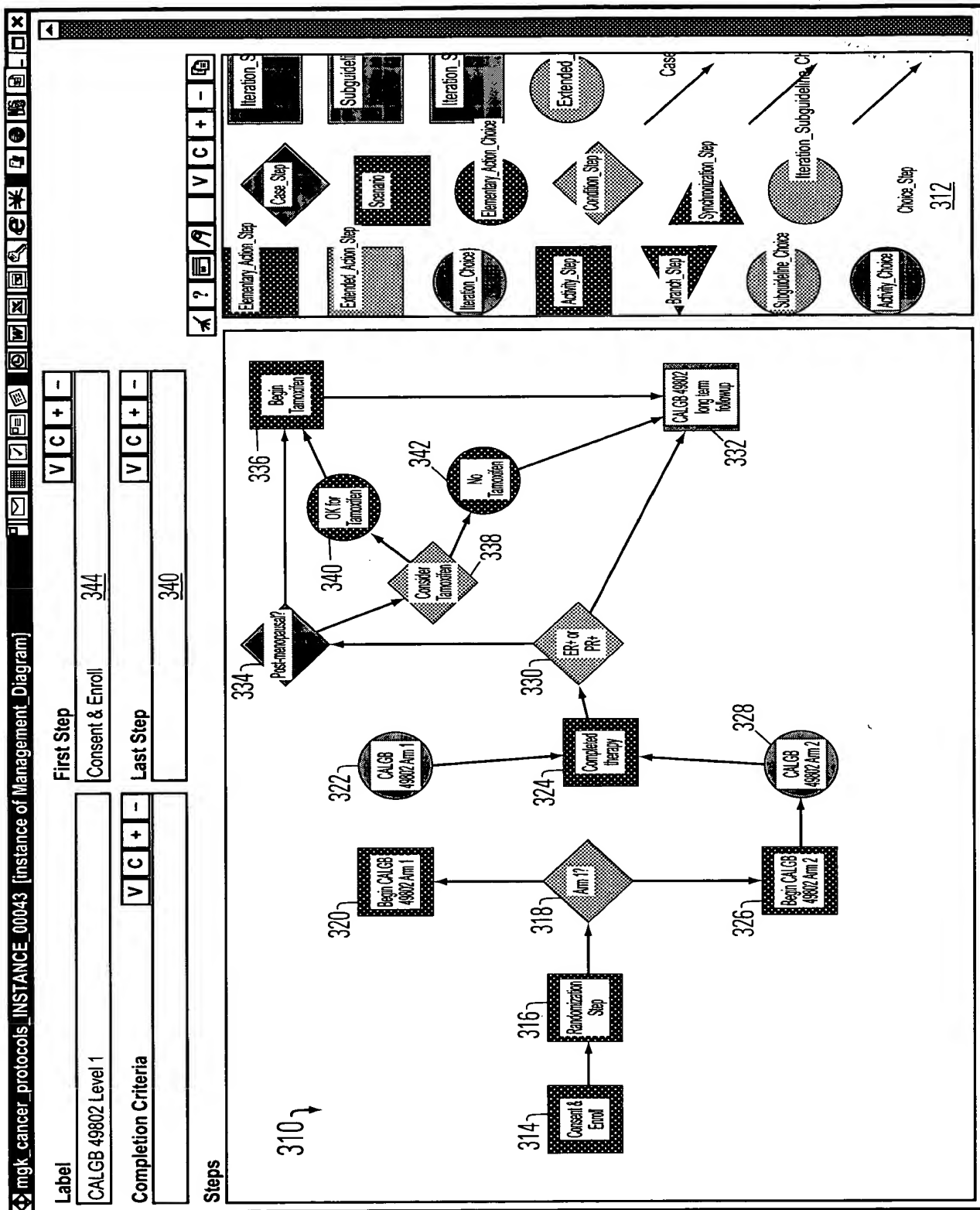
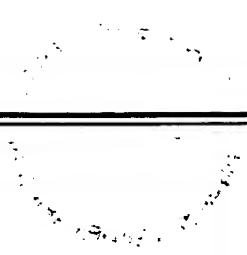


FIG. 3



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mgk_cancer_protocols_INSTANCE_00063 [instance of Consultation_Act..]

Label		mgk_cancer_protocols_INSTANCE_00063 [instance of Consul	
CALGB 49802: Collect Stratification Variabl		<ul style="list-style-type: none">◆ Evaluate lymph node status◆ Evaluate menopausal status◆ Evaluate estrogen receptor status◆ Evaluate progesterone receptor status	
Followed By	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -		
Rule In	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -	References	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
Rule Out	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -		

FIG. 5

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2011-02-20 18:44:56

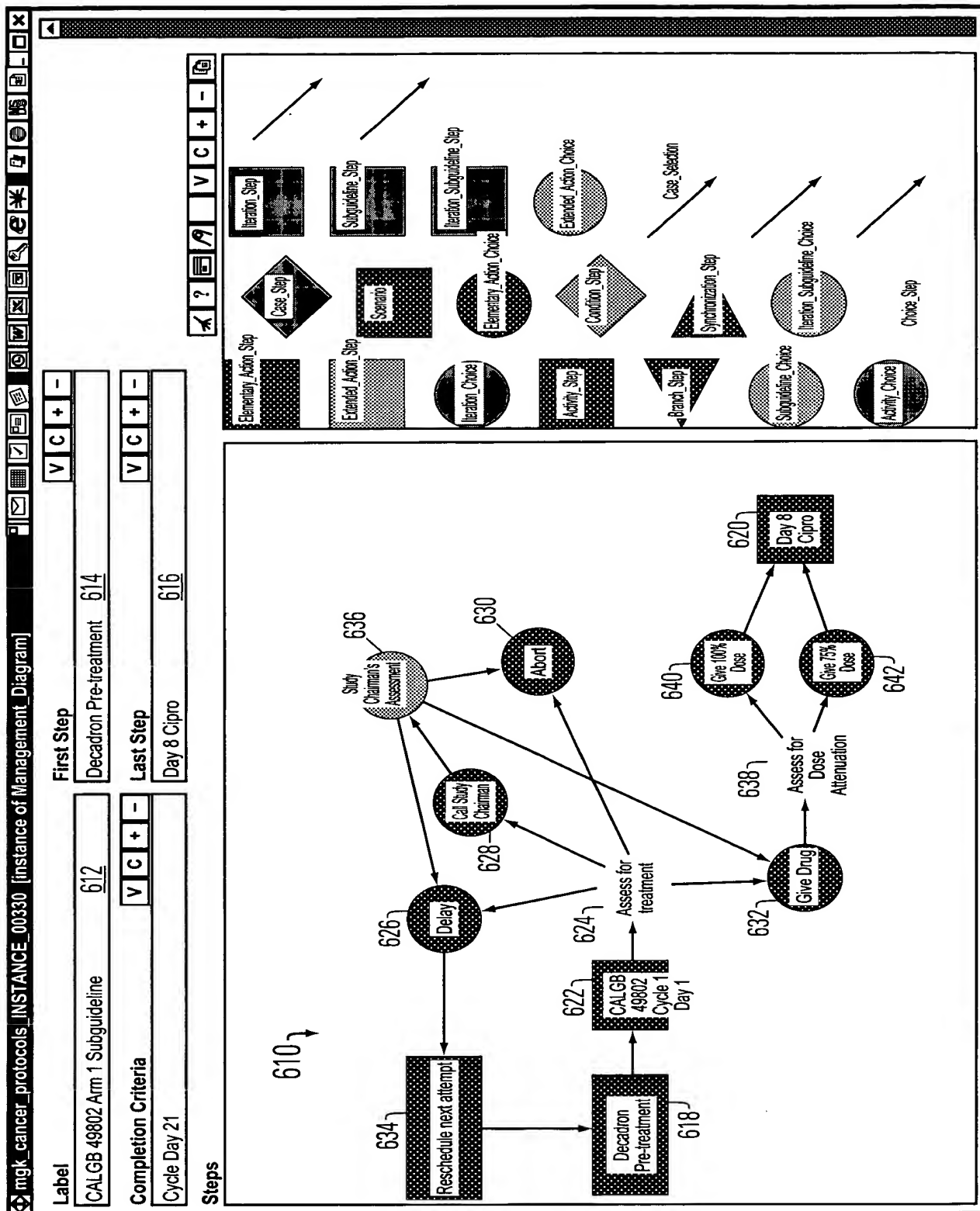


FIG. 6

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201120 "1844650

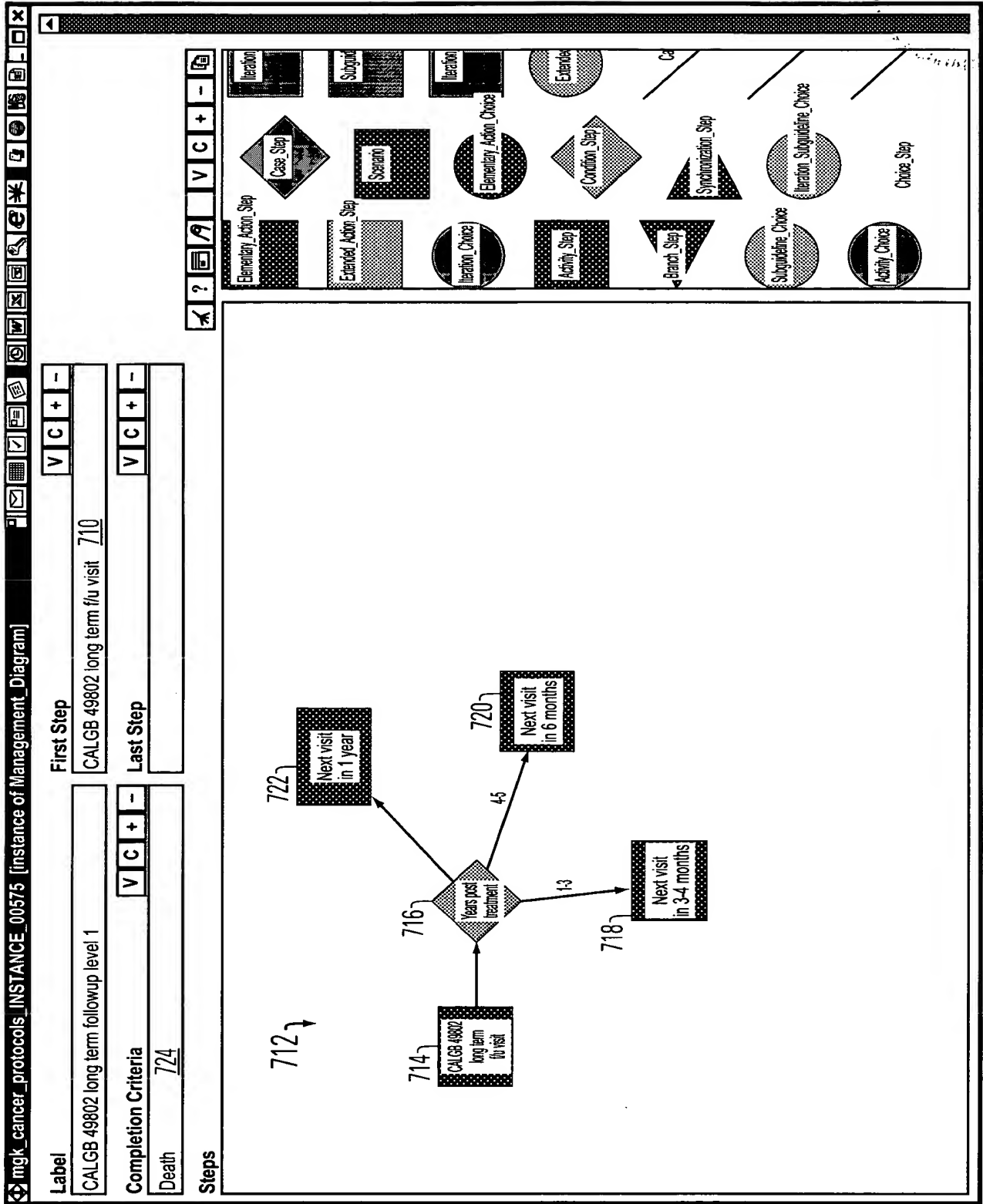


FIG. 7

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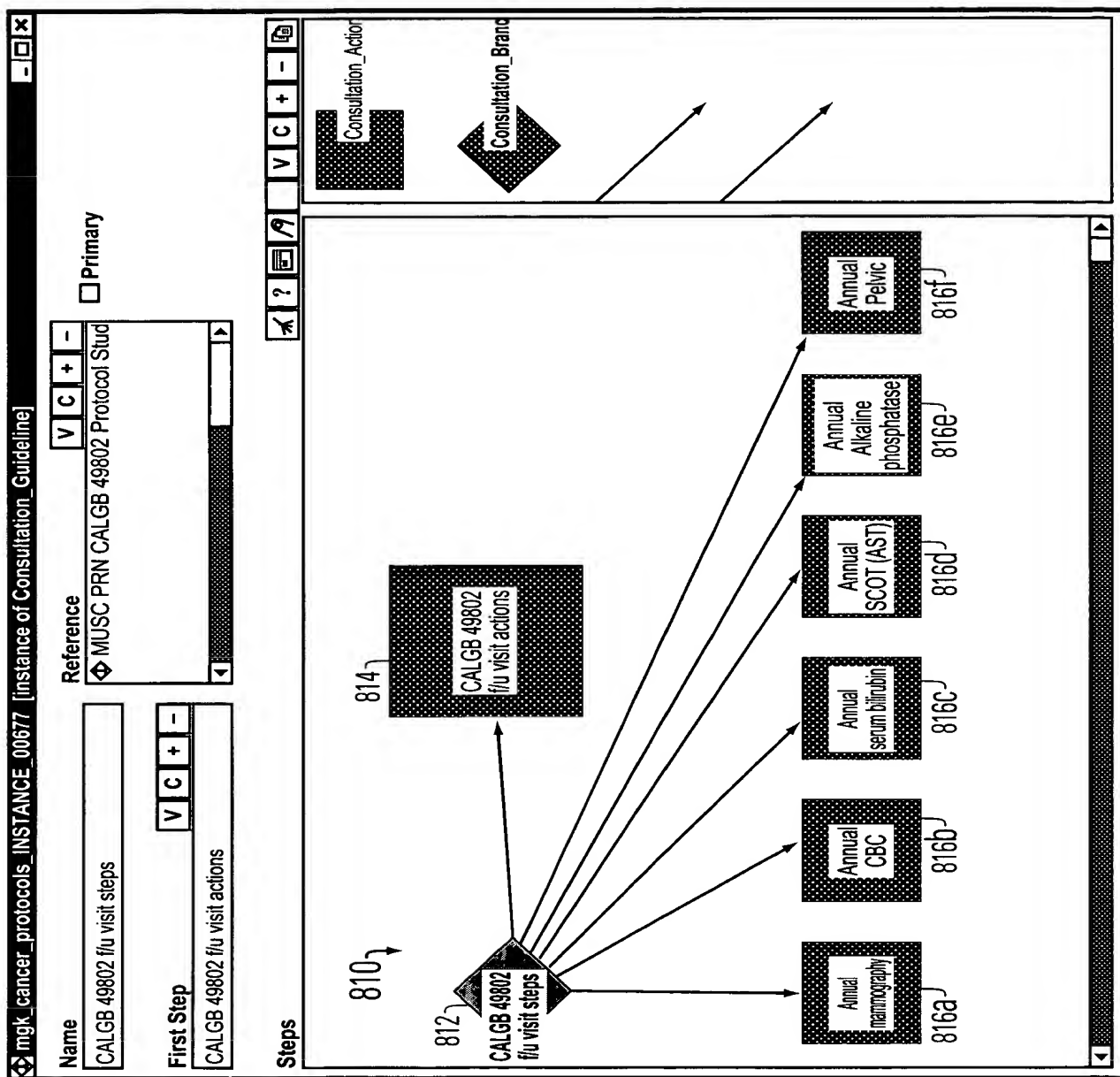


FIG. 8

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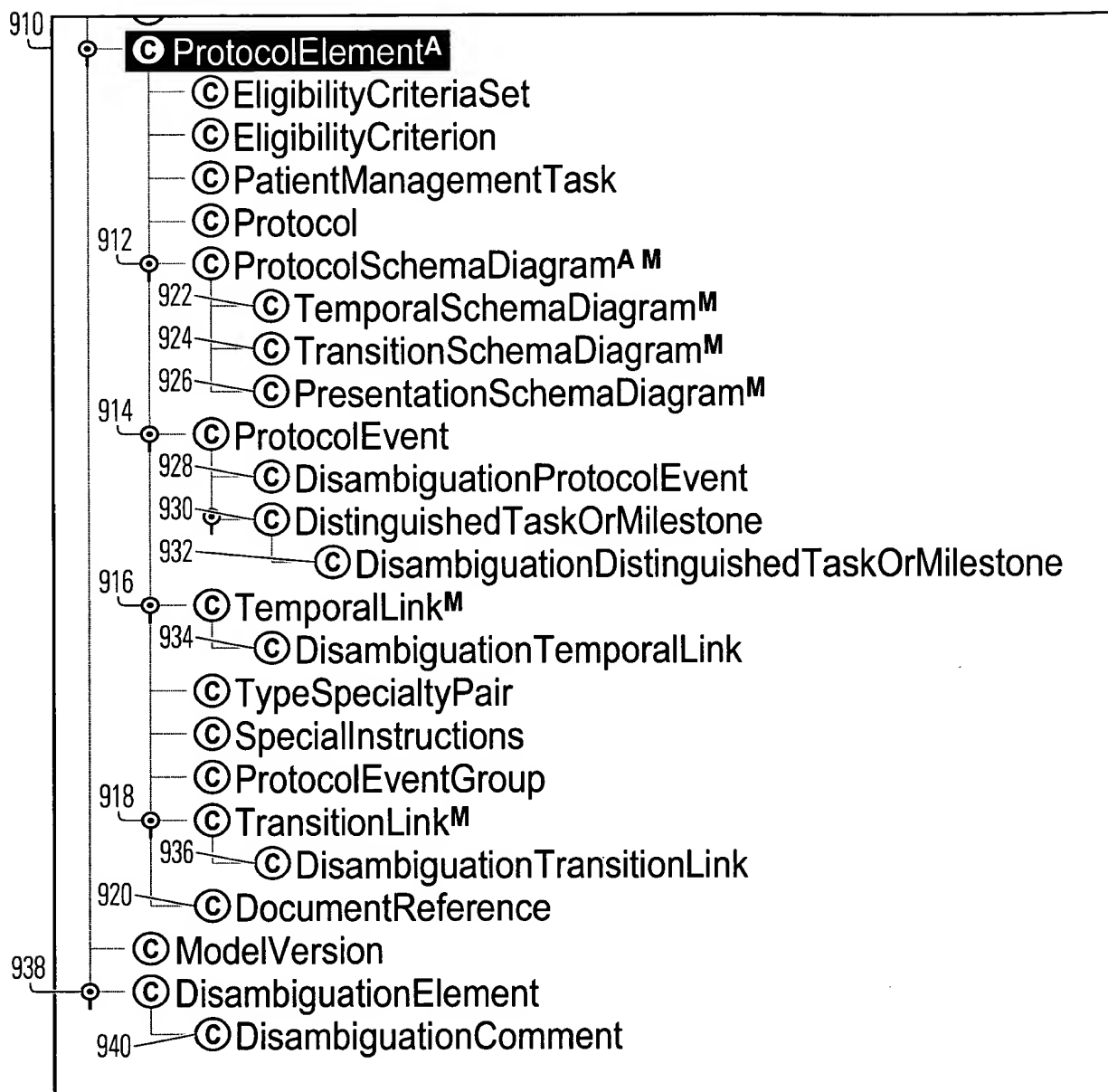


FIG. 9

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910

© ProtocolElement

Name	Documentation	Constraints
ProtocolElement	The superclass for all objects in the FastTrack protocol model.	

Role

Abstract^A

Template Slots

Name	Type	Cardinality	Other Facets
1010 [S] disambiguationComments	Instance	multiple	classes={DisambiguationComment}
[S] drillDown	Boolean	single	default={false}
1012 [S] encodingComments	String	single	
1014 [S] longDescription	String	single	
[S] shortDescription	String	required single	

FIG. 10

FastTrack Protocol | Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes

Forms

Instances

Relationship: Subclass V C X

⊙ :THING^A

⊙ :SYSTEM-CLASS^A

⊙ Diagram_Entity

⊙ Date

⊙ ProtocolElement^A — 1112

⊙ EligibilityCriteriaSet — 1124

⊙ EligibilityCriterion

⊙ PatientManagementTask — 1130

⊙ Protocol — 1116

⊙ ProtocolSchemaDiagram^M — 1132

⊙ Visit — 1128

⊙ VisitToVisitTransition^M

⊙ DiseaseArea

⊙ Arm — 1150

⊙ WeightedPath — 1152

⊙ ApplicationArea

⊙ VisitCycle — 1154

⊙ Disease^A

⊙ DiseaseQualifiers^A — 1110

⊙ ModelVersion

⊙ Protocol (instance of rdfs:Class)

Name

Protocol

Constraints

Documentation

The document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol also usually gives the background and

Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
protocolSchemaDiagram	Instance	Single		classes={ProtocolSchemaDiagram}
protocolTitle	String	Single		
quickScreenCriterion	Symbol	Single		
rdfs:isDefinedBy	Instance	Single		1127 values={Prostate Cancer, Colorectal Cancer, Breast Cancer}
rdfs:seeAlso	Instance	Single		1122 classes={URI, rdfs:Resource}
resource uri	Instance	Single		classes={URI, rdfs:Resource}
shortDescription	String	Single		classes={URI}
siteAccrualTarget	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		
sponsor	String	Single		
sponsorAccrualTarget	String	Single		
studyChair	String	Single		
trialPhase	Symbol	Single		1118 values={Phase I, Phase II, Phase IV, Phase, PhaseII}
trialStatus	Symbol	Single		values={On Hold, Terminated, Active}

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

66 5 V + -

FIG. 11

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FastTrack Protocol_INSTANCE_00212 [instance of Protocol]

ProtocolTitle A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion v	Version Update #1
ProtocolIdentifier CALGB 9840	VersionDate December 15, 1998
OfficialSourceDocument http://pm.musc.edu/research/protocol/deptmed/divhonc/bi	EligibilityCriteriaSet <div> <input type="button" value="V"/> <input type="button" value="C"/> <input type="button" value="+"/> <input type="button" value="-"/> </div> <div> <input checked="" type="checkbox"/> CALGB 9840 Eligibility Criteria 1212 </div>
ShortDescription CALGB 9840	LongDescription
StudyChair Andrew D. Seidman, M.D.	
Sponsor CALGB	
QuickScreenCriterion Breast Cancer	
Sponsor To compare "standard" (S) paclitaxel at 175 mg/m2 via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m2 via 1-hour infusion every week	
TrialStatus Active	AccrualStatus Open for accrual
TrialPhase Phase III	TrialType Cooperative group
FirstVisit Screening Visit	
ProtocolSchemaDiagram CALGB 9840 Schema 1214	

FIG. 12

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914

© ProtocolEvent

Name: ProtocolEvent

Role: Concrete

Documentation: This class is used to represent a single patient visit during the course of a clinical protocol.

Constraints: [V] [C] [] []

Template Slots: [V] [V] [C] [X] [] []

Name	Type	Cardinality	Other Facets
1010 [S] disambiguationComments	Instance	multiple	classes={DisambiguationComment}
[S] drillDown	Boolean	single	default={false}
[S] encodingComments	String	single	
1312 [S] eventType	Symbol	single	allowed-values={Screening, Treatme...}
[S] incomingLinks	Instance	multiple	classes={TemporalLink}
1012 [S] isMilestone	Boolean	single	default={false}
1310 [S] longDescription	String	single	
1314 [S] managementTasks	Instance	multiple	classes={PatientManagementTask}
1014 [S] outgoingLinks	Instance	multiple	classes={TemporalLink}
[S] shortDescription	String	required single	

FIG. 13

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2011201844660

2 day f/u for Visit 1 (DisambiguationProtocolEvent)

ShortDescription
2 day f/u for Visit 1

EventType
Treatment

LongDescription
These labs must be obtained in the morning.

Management Tasks V C + -
Phone F/U
Creatinine
Ionized Ca
Mg
PO4
CBC with Diff and plt

Incoming Links V C + -
Visit 1 to Visit 1 f/u

EncodingComments

OutgoingLinks V C + -

DisambiguationComments V C + -
Inconsistent tasks in tx plan and assessment
1410

FIG. 14

15/41

916

© TemporalLink (Connector_Metaclass)

Name	Constraints	V	C	+	-	Documentation
TemporalLink						This class a temporal constraint or anchoring between two visits.
Role						
Concrete						

Template Slots

Name	Type	Cardinality	Other Facets
disambiguationComments	Instance	multiple	classes={DisambiguationComment}
dominant	Boolean	single	default={false}
drillDown	Boolean	single	default={false}
encodingComments	String	single	
first_object ⁰¹	Instance	single	classes={ProtocolEvent}
longDescription	String	single	
maximumRelativeOffset	Integer	single	
minimumRelativeOffset	Integer	single	
offsetUnits	Symbol	required single	allowed-values={Years,Months,Week...
preferredRelativeOffset	Integer	single	
second_object ⁰¹	Instance	single	classes={ProtocolEvent}
shortDescription	String	required single	

1010

510

1012

1518

1516

1522

1520

1512

1014

FIG. 15

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Screening to Rheumatoid Factor (TemporalLink)

ShortDescription
Screening to Rheumatoid Factor

FromEvent (first_object) [V] [C] [+] [-]
Screening

preferredRelativeOffset
[]

ToEvent (second_object) [V] [C] [+] [-]
Rheumatoid Factor

MinimumRelativeOffset
[] -180

MaximumRelativeOffset
[] -1

OffsetUnits
Days [v] ☐ Dominant

DisambiguationComments [V] [C] [+] [-]
[]

EncodingComments
[]

FIG. 16

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FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

φ:THING^A

- ⊙:SYSTEM-CLASS^A
- ⊙Diagram_Entity
- ⊙Date
- ⊙ProtocolElement^A — 1112
- ⊙EligibilityCriteriaSet — 1124
- ⊙EligibilityCriterion
- ⊙PatientManagementTask — 1130
- ⊙Protocol — 1116
- ⊙ProtocolSchemaDiagram^M — 1132
- ⊙Visit — 1128
- ⊙VisitToVisitTransition^M
- ⊙DiseaseArea
- ⊙Arm
- ⊙WeightedPath
- ⊙ApplicationArea
- ⊙VisitCycle
- ⊙Disease^A
- ⊙DiseaseQualifiers^A
- ⊙ModelVersion

Ⓢ Visit (Instance of rdfs:Class)

Name Visit

Constraints V C + -

Documentation
An actual encounter between the provider and a patient on study. A number of possible visits are associated with a study (Protocol).

Role Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
dataManagementTasks	Instance	Multiple		classes={ManagementTask}
longDescription	String	Single		
patientManagementTasks	Instance	Multiple		classes={ManagementTask}
possibleVisitTransitions	Instance	Multiple		classes={VisitToVisitTransition}
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 66 5 V + -

Superclasses + -

Ⓢ FastTrackClass

1110

1710

FIG. 17

FastTrack Protocol INSTANCE 00014 [instance of Visit]

ShortDescription

Arm A Treatment Visit

PossibleVisitTransitions

Arm A Treatment to Arm A Treatment Retry #1

Arm A Treatment to Long Term Followup

Arm A Treatment Visit to Arm A Treatment Visit

DataManagementTasks

Submit Form C-116

Submit Form C-118

Submit Form C-080

Submit Form C-344 + Form C-080 (*)

Submit Form C-344 + Form C-272 (*)

Submit Form C-113 (*)

Submit Form C-260 (*)

Submit Form C-300 (*)

PatientManagementTasks

Comm granulocytes >= 1500 / ul

Confirm no G-CSF given in past 24 hours

Give Dexmethosone 10 mg IV, 30 minutes

Give Diphenhydramine 50 mg IV, 30 minutes

Give Cimetidine 300 mg IV, 30 minutes

Give anti-emetics (*)

Give Arm A Paclitaxel treatment

Give G-CSF (*)

Evaluate Patient Response

Schedule next visit

LongDescription

Arm A of the CALG 9840 consists of treatment with Paclitaxel 175 mg/m2 administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be >= 1500/ul and platelet count must be >= 100,000 / ul on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression (>50% increase in product of bi-dimensional measurements).

SiteLongDescription

SiteShortDescription

FIG. 18



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FastTrack Protocol_INSTANCE_00206 [instance of ManagementTask]

ShortDescription

Give Arm A Paclitaxel treatment

LongDescription

Give Paclitaxel 175 mg/m² IV, 3hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be $\geq 1500/\mu\text{l}$ and platelet count must be $\geq 100,000/\mu\text{l}$ on day 1 of each cycle in order to proceed with the Paclitaxel infusion. Patients must receive the pre-medication prior to Paclitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.

Expected toxicities:

The dose-limiting toxicity of Paclitaxel is neutropenia. Other known toxicities include nausea and vomiting, diarrhea, stomatitis, mucositis, pharyngitis, typhilitis, ischemic colitis, bradycardia, atrial arrhythmia, hypotension, hypertension, sensory (taste), peripheral neuropathy, seizures, mood, hepatic encephalopathy, acute anaphylactoid and urticarial reactions, flushing, rash, pruritis, increased SGOT, SGPT, bilirubin and/or alkaline phosphatase, hepatic failure, alopecia, fatigue, myalgia, light-headedness, myopathy, visual changes (sensation of flashing lights, blurred vision). Local infiltration with Paclitaxel will cause mild local symptoms (erythema, discomfort, induration) that usually resolve within a week. If infiltration occurs, there is the rare possibility of ulceration or rash. Seizure have been reported rarely in association with Paclitaxel use.

Dose Modifications:

Allergic reactions: Patients with grade 1 or 2 allergic reactions may have treatment continued without modifications. Patients with grade 3 or 4 allergic reactions who are responding to treatment may remain on protocol therapy after discussion with Study Chair. Such patients are at risk for recurrent allergic reactions. As a first maneuver, retreatment after premedication with oral recurrent allergic reactions. As a first maneuver, retreatment after premedication with oral dexamethasone 20 mg at 12 and 6 hours pre-administration of Paclitaxel, along with IV H1 and H2-receptor antagonist should be attempted. If necessary, thereafter, infusion rate adjustments will be considered and additional premedications will be administered. These patients must be informed of the potential risks of recurrent allergic reactions and must be carefully monitored.

Hematologic Toxicity: Patients are to be managed as clinically indicated. Colony stimulation factors (G-CSF) should be used in the manner described below. Future doses should be discussed with the Study Chair.

SiteLongDescription

FIG. 20

21/41

FastTrack Protocol_INSTANCE_00196 [instance of ManagementTask]

ShortDescription
Submit Form C-116

LongDescription
Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.

SiteLongDescription

SiteShortDescription

FIG. 21



23/41

1818

FastTrack Protocol_INSTANCE_00023 [instance of VisitToVisit Transition]

ShortDescription	PreferredRelativeTime
Arm A Treatment to Arm A Treatment Retry #	7
First Object <input type="button" value="V"/> <input type="button" value="C"/> <input type="button" value="+"/> <input type="button" value="-"/>	MaximumRelativeTime
Arm A Treatment Visit	7
Second Object <input type="button" value="V"/> <input type="button" value="C"/> <input type="button" value="+"/> <input type="button" value="-"/>	MinimumRelativeTime
Arm A Treatment Retry #1	7

LongDescription

If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.

SiteLongDescription

☐ **IsPreferredTransition**

SiteShortDescription

2310

FIG. 23

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FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

Relationship:

- THINGA
- SYSTEM-CLASSA
- Diagram_Entity
- Date
- ProtocolElementA-1112
- EligibilityCriteriaSet-1124
- EligibilityCriterion
- PatientManagementTask-1130
- Protocol-1116
- ProtocolSchemaDiagramM-1132
- Visit-1128
- VisitToVisitTransitionM-2210
- DiseaseArea
- Arm
- WeightedPath
- ApplicationArea
- VisitCycle
- DiseaseA
- DiseaseQualifiersA
- ModelVersion

ProtocolSchemaDiagram (instance of Network_Metaclass)

Name: ProtocolSchemaDiagram V C + -

Role: Concrete

Documentation: The ProtocolSchemaDiagram is the part of the protocol which details the design of the trial. A protocol schema's first visit is always at least one screening visit, which is assumed

Template Slots

Name	Type	Cardinality	Default	Other Facets
connectors	Instance	Multiple		classes={VisitToVisitTransition}
diagramNodes	Instance	Multiple		classes={Visit}
last_divider_location	Integer	Single		
layout_information	Instance	Multiple		classes={ObjectLocation}
longDescription	String	Single		
main_panel_height	Integer	Single		
main_panel_width	Integer	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Node Slot

diagramNodes V C + -

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Superclasses

- FastTrackClass
- NetworkA

FIG. 24

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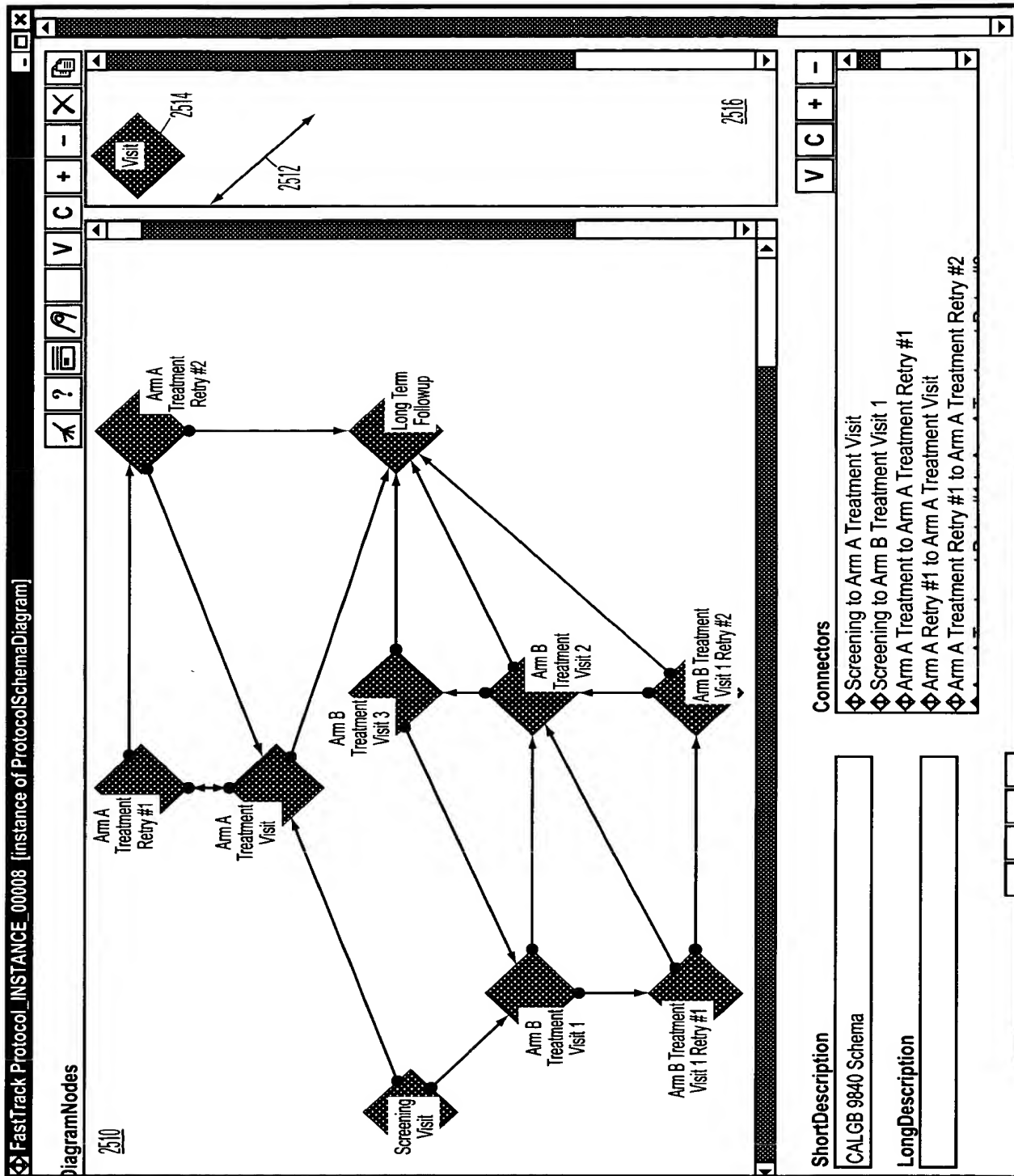


FIG. 25

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940

© DisambiguationComment

Name: DisambiguationComment

Role: Concrete

Documentation

Constraints

Template Slots

Name	Type	Cardinality	Other Facets
conceptualProtocolSection	Symbol	multiple	allowed-values={Protocol Summary,...
documentReferences	Instance	multiple	classes={DocumentReference}
Impact Type	Symbol	multiple	allowed-values={Safety,Efficacy-prim..
Issue	String	single	
Potential Impact	String	single	
Protocol text	String	single	
Recommendation	String	single	
Severity Level	Symbol	single	allowed-values={Level One,LevenTw..
Short Description	String	single	

FIG. 26



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Protocol Protégé-2000 [D:\Work\Sample\Protocol.pprj]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

©:THINGA

- ©:SYSTEM-CLASS^A
- © Diagram_Entity
- © Date
- © ProtocolElement^A — 1112
- © EligibilityCriteriaSet — 1124
- © EligibilityCriterion
- © PatientManagementTask — 1130
- © Protocol — 1116
- © ProtocolSchemaDiagram^M — 1132
- © Visit — 1128
- © VisitToVisitTransition^M
- © DiseaseArea
- © Arm — 1150
- © WeightedPath — 1152
- © ApplicationArea
- © VisitCycle — 1154
- © Disease^A
- © DiseaseQualifiers^A
- © ModelVersion

1110

© Arm (instance of :STANDARD.CLASS)

Name Arm

Constraints V C + -

Documentation

Role Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
drillDown	Boolean	single	false	
encodingComments	String	single		
isObsolete	Boolean	single	false	
longDescription	String	single		
obsoleteVisits	Instance	multiple		classes={Visit, VisitCycle}
shortDescription	String	single		
Visits — 2812	Instance	multiple		classes={Visit, VisitCycle}

2810

Superclasses

- © ProtocolElement^A

FIG. 28

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[instance of Arm]

ShortDescription
Arm A —2710

LongDescription
Arm A: Gemcitabine and Irinotecan HCl
(CPT-11)

EncodingComments
Editorial change

Visits

V C + -

- ◆ Screening —2712
- ◆ Arm A, Day 1 —2722
- ◆ Arm A, Day 8 —2724
- ◆ Arm A, Day 15, Rest —2726
- ◆ End of Treatment —2718
- ◆ Follow-up Visit —2720

ObsoleteVisits

V C + -

☐ IsObsolete ☐ DrillDown

09974781.024102

FIG. 29

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Protocol Protégé-2000 [D:\Work\Sample\Protocol.pprj]
Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

ThingA
SYSTEM-CLASSA
Diagram_Entity
Date
ProtocolElementA
EligibilityCriteriaSet
EligibilityCriterion
PatientManagementTask
Protocol
ProtocolSchemaDiagramM
Visit
VisitToVisitTransitionM
DiseaseArea
Arm 1150
WeightedPath 1152
ApplicationArea
VisitCycle 1154
DiseaseA
DiseaseQualifiersA
ModelVersion

Superclasses
Arm

WeightedPath (instance of :STANDARD-CLASS)

Name
WeightedPath

Constraints
V C + -

Documentation

Role
Concrete



Template Slots


Name	Type	Cardinality	Default	Other Facets
drillDown	Boolean	single	false	
encodingComments	String	single	false	
isObsolete	Boolean	single	false	
longDescription	String	single		
obsoleteVisits	Instance	multiple		classes={Visit,VisitCycle}
pathWeight	Integer	single	1	
shortDescription	String	single		classes={Visit,VisitCycle}
Visits	Instance	multiple		

FIG. 30

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3110

 [instance of WeightedPath] 

ShortDescription <input type="text" value="Arm A Path"/>	Visits 
LongDescription <input type="text"/>	<ul style="list-style-type: none">◆ Screening →2712◆ Arm A Cycle →2736◆ End of Treatment →2718◆ Follow-up cycle →2720
EncodingComments <input type="text"/>	PathWeight <input type="text" value="1"/>

☐ IsObsolete ☐ DrillDown

FIG. 31

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Protocol Protégé-2000 [D:\Work\Sample\Protocol.pprj]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

φ:THING^A

- ⊙:SYSTEM-CLASS^A
- ⊙Diagram_Entity
- ⊙Date
- ⊙ProtocolElement^A
- ⊙EligibilityCriteriaSet
- ⊙EligibilityCriterion
- ⊙PatientManagementTask
- ⊙Protocol
- ⊙ProtocolSchemaDiagram^M
- ⊙Visit
- ⊙VisitToVisitTransition^M
- ⊙DiseaseArea
- ⊙Arm — 1150
- ⊙WeightedPath — 1152
- ⊙ApplicationArea
- ⊙VisitCycle — 1154
- ⊙Disease^A
- ⊙DiseaseQualifiers^A
- ⊙ModelVersion

⊙ VisitCycle (instance of :STANDARD.CLASS)

Name VisitCycle

Constraints V C + -

Role Concrete

Documentation

Template Slots

Name	Type	Cardinality	Default	Other Facets
cycleCount — 3214	Integer	single	1	
drillDown	Boolean	single	false	
encodingComments	String	single		
isObsolete	Boolean	single	false	
longDescription	String	single		
shortDescription	String	single		
visitInCycle — 3212	Instance	multiple		classes=(Visit,VisitCycle)

3210





Superclasses





- ⊙ ProtocolElement^A

FIG. 32

33/41

2736

 [instance of VisitCycle]   

ShortDescription <input type="text" value="Arm A Cycle"/>	VisitsInCycle     <ul style="list-style-type: none">◆ Arm A, Day 1 → 2722◆ Arm A, Day 8 → 2724◆ Arm A, Day 15, Rest → 2726
LongDescription <input type="text"/>	
EncodingComments <input type="text"/>	CycleCount <input type="text" value="3"/>

☐ DrillDown ☐ IsObsolete

FIG. 33

DECEMBER 1970

FIG. 34

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Inconsistent tasks in tx plan and assessment table (DisambiguationComment)

ShortDescription Inconsistent tasks in tx plan and assessment table	Severity Level Level One	Document Page p. 13, p. 31
Protocol Text "b) Baseline safety evaluation --- laboratory tests 2 days following the first infusion will include: ionized calcium, magnesium, phosphorus, creatinine, and CBC..."		Additional reference comments
Issue The assessment schedule on page 31 does not list the creatinine.	Protocol Section Treatment Plan Schedule of Events	
Potential Impact A safety assessment could be missed, having the potential impact of missing the timely deflection of an adverse event.	Impact Type Safety	
Recommendation Add in the creatinine task to the assessment summary.		

FIG. 35

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920

© DocumentReference

Name: DocumentReference

Role: Concrete

Documentation:

Constraints:

Template Slots

Name	Type	Cardinality	Other Facets
[S] addlDocRefInfo	String	single	
[S] disambiguationComments	Instance	multiple	classes={DisambiguationComment}
[S] drillDown	Boolean	single	default={false}
[S] encodingComments	String	single	
[S] literalSponsorSectionName	String	single	
[S] longDescription	String	single	
[S] pageNumber	String	single	
[S] protocolText	String	single	
[S] sectionReferenceNumber	String	single	
[S] shortDescription	String	required single	

3610

FIG. 36

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31 (Document Reference)

PageNumber

31

SectionReferenceNumber

11.1.2

LiteralSponsorSectionName

VisualFunction and MSFC Practice Tests

AddIDocRefInfo

Examining Technician instructions

ProtocolText

"...performed three times within 35 days prior to randomization, with at least 5 days between any two evaluations.."

EncodingComments

FIG. 37

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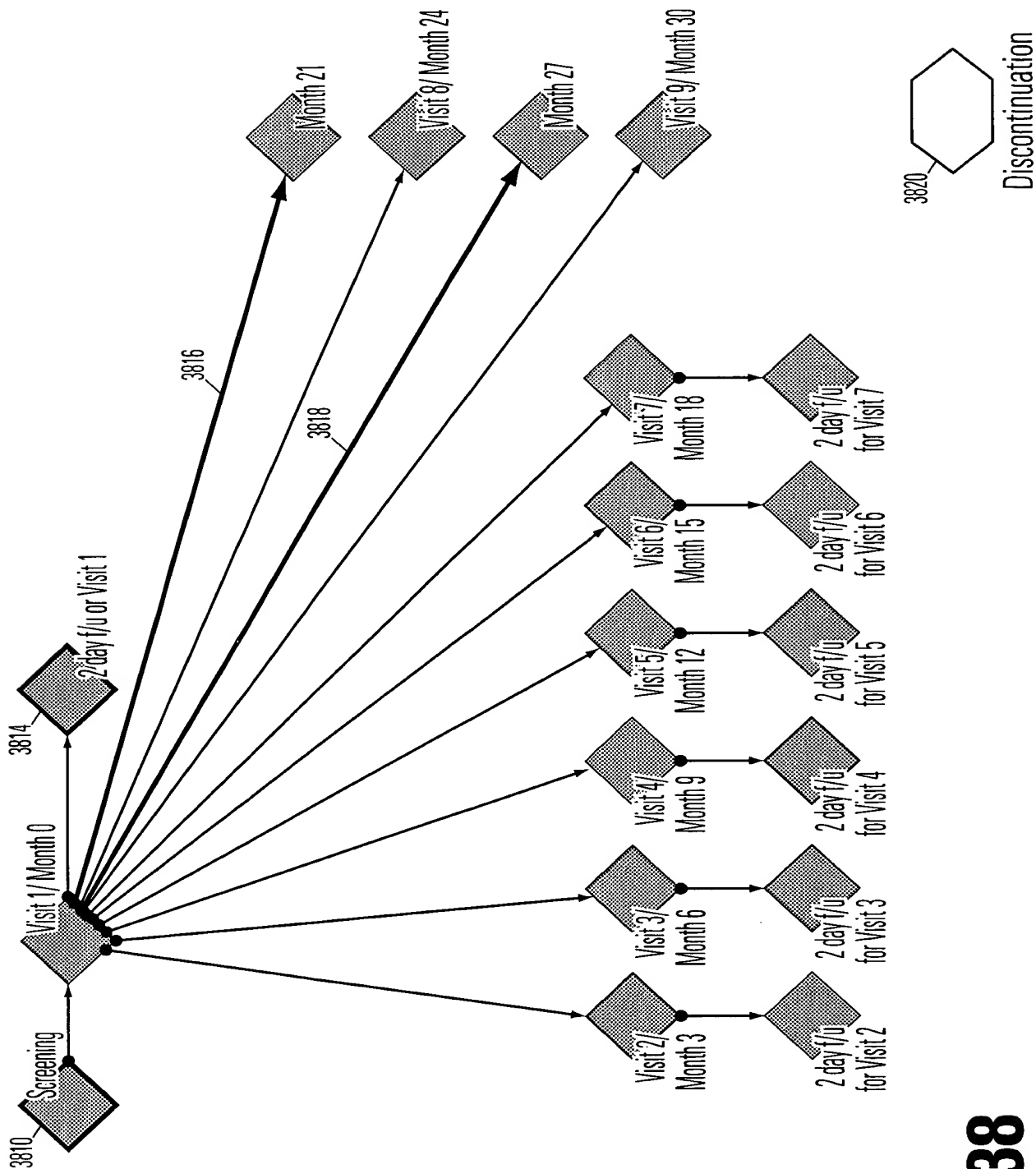


FIG. 38

201120" FEB 24 2000

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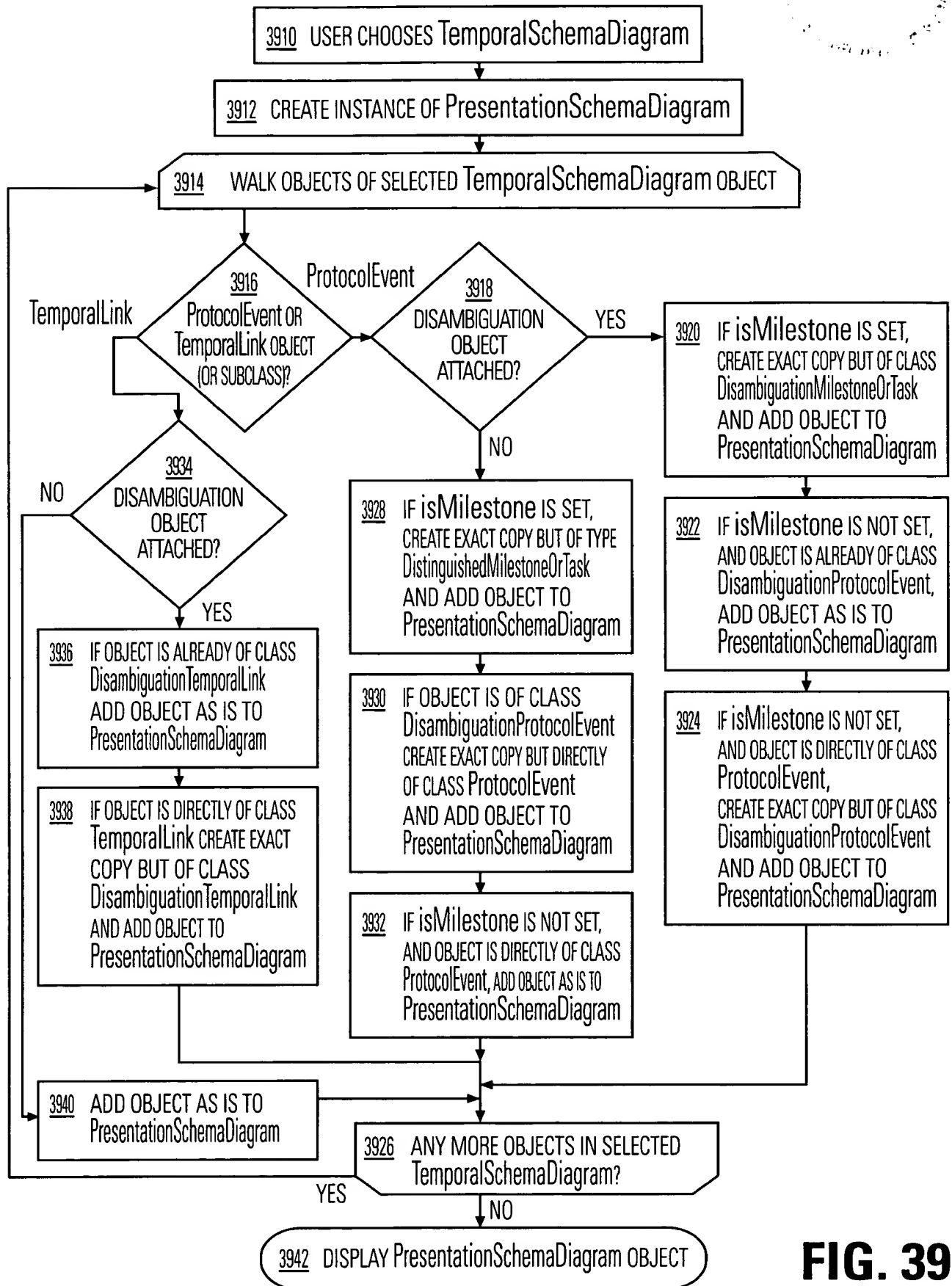


FIG. 39

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DISAMBIGUATION FINDINGS

Item	Impact Type	Protocol Section	Description	Document Reference
1	Safety Efficacy- primary Efficacy- secondary	Protocol Summary Study Flow Chart	<p>Issue:</p> <p>The description in the Protocol Synopsis of when assessments should be performed after 16 weeks is not consistent with Appendix I Schedule of Assessments.</p> <p>Potential Impact:</p> <p>Confusion as to when to perform these evaluations (clinical parameters and safety assessments) could result in inconsistent and inaccurate collection of data for the study.</p> <p>Recommendation:</p> <p>Revise sentence in the Protocol Synopsis to read, "After 16 weeks these evaluations will be performed every two to "four" months..." in order to be consistent with the timepoints indicated in Appendix I Schedule of Assessments.</p>	<p><i>Pg. 12; Section Protocol Synopsis; Procedure; Paragraph 6:</i></p> <p>"Clinical parameters (ACR core set) and safety assessments (adverse events and laboratory parameters) will be performed at baseline and then at monthly intervals up to 16 weeks. After 16 weeks these evaluations will be performed every two to three months, up to 104 weeks."</p>

FIG. 40

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Item	Impact Type	Protocol Section	Description	Document Reference
4	Safety Accrual	Screening Assessments Study Flow Chart	<p>Issue:</p> <p>The protocol text specifies that if an analysis with evidence of seropositivity was performed within 6 months before screening, then rheumatoid factor testing will not have to be performed at screening. However, this is not noted in Appendix I Schedule of Assessments.</p> <p>Potential Impact:</p> <p>Unnecessary analysis performed at screening.</p> <p>Recommendation:</p> <p>Add a footnote to the Rheumatoid Factor assessment in Appendix I to clarify that documented evidence of seropositivity is acceptable as screening data if obtained within 6 months before screening.</p>	<p><i>Pg. 28; Section 8.6.2; Rheumatoid Factor:</i> "Unless there is documented evidence of rheumatoid factor titre within 6 months before screening a blood sample for this analysis will be taken."</p> <p><i>Pg. 41; Section Appendix I; Schedule of Assessments</i></p>

FIG. 41